REMARKS

Claims 88-105 are currently pending in the subject application. Applicant has not hereinabove added, amended or cancelled any claims.

Rejection Under 35 U.S.C. §112, Written Description

The Examiner rejected claims 89-105 as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that the application has a single example of a tablet which contains, inter alia, 2.5mg oxandrolone. The Examiner further stated that the "application merely mentions 10-milligram dosage, but does not disclose further information as to the carrier and particular forms."

In response, applicant respectfully traverses the Examiner's rejection. The specification at page 5, lines 19-22 supports the "unit dosage form" of the claimed composition. The specification states that "...in accordance with this invention, the active ingredient oxandrolone is combined with solid or liquid pharmaceutical carriers and formulated in unit dosage form ..." Furthermore, lines 27-30 note that the dose can be "as low as about" 2.5 mg and "as high as about" 20mg. Page 4, line 4 recites that a dose used in the study was a 10mg dose.

Furthermore, the Examiner has acknowledged certain oxandrolone tablet compositions were known in the art. This, taken in context of the rest of the specification, clearly conveys to one of *ordinary skill in the art* applicant's possession of the invention

as recited in the claims. In regard to this, applicant notes that, as recited in M.P.E.P §2163:

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge.... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

Accordingly, applicant respectfully submits the invention recited in the pending claims is fully described in the subject application. Applicant respectfully requests that the Examiner clarify why one of *ordinary skill in the art* would not recognize applicant to be in possession of the invention as claimed if the Examiner intends to maintain the written description rejection.

Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 88-105 under 35 U.S.C. §103(a) as allegedly obvious over Metcalf et al. (of record) in view of ANAVAR® (of record) and Babu et al. (U.S. Patent No. 5,073,380) and "further in view of applicants' admission at page 7." The Examiner alleged, inter alia, that it would have been prima facie obvious to one of ordinary skill in the art to make a dosage composition comprising 10mg oxandrolone with particular excipients, and that 10mg would have been obvious in view of the "the fact that it [would] have been used in the amount of 10mg, 20mg, and up to 150mg." The Examiner stated that "making a tablet with 10mg of oxandrolone for those use more than 10mg a time."

The Examiner also suggested that because Metcalf states that the optimum dose is 25-30mg/day, a "10 mg dose would have been obvious for a three times a day regimen".

Applicant's response

In response, applicant respectfully traverses the Examiner's rejection.

1. Impermissible Hindsight

Applicant notes that there is no "three times a day" regimen mentioned in Metcalf or in the reminder of the combination of references. Metcalf discloses a one-time a day regimen (see page 60). Were hindsight appropriate, it would be possible to make up any convenient regimen to arrive at the claimed invention. Clearly, there is no suggestion for this in the prior art, and the 10mg unit dose form is being recreated through impermissible hindsight based on knowledge of *applicant's* 10mg unit dose form. For this reason alone, the rejection is improper. The Examiner has reconstructed applicant's claimed 10mg unit dose form by selecting one of several possible daily doses daily doses from Metcalf, then dividing it by an arbitrary *n*, where *n* = the number of times per day, to somehow arrive at the claimed invention, without any reasoned basis for arriving at *n*, other than that it results in applicant's invention. This is impermissible hindsight.

2. Art-recognized problems teach away from Examiner's suggestion

Applicant further notes that due to the art-recognized problems of (1) patient compliance and (2) pill-burden, a *three* times a day regimen as suggested by the Examiner is not an obvious choice. In fact, pill-burden argues *against* the Examiner's

selection of the three times per day regimen.

3. Art teaches away from Examiner's suggestion

Applicant respectfully reminds the Examiner that Metcalf explicitly teaches that the optimal combined daily amount is 25-30mg per day (see Metcalf, p63) and discuss the "variable response at low dose levels" (see Metcalf, p60). Applicant maintains that one of ordinary skill in the art would therefore not be motivated to produce a 10mg unit dosage form based on Metcalf's express teaching that such a low dose is not useful.

4. Declaration under 37 C.F.R. §1.132

In support of their position, applicant also attaches hereto as **Exhibit 1** a Declaration under 37 C.F.R. §1.132 by Dr. Faith Ottery. Applicant notes that Dr. Ottery is employed by Savient Pharmaceuticals to who the subject application is assigned. The Declaration supports the position that the claimed 10mg unit dose form is not obvious over the cited combination of prior art.

As described in the Declaration, the cited combination of prior art can be reasonably only interpreted to suggest a 25-30mg unit dosage form for oxandrolone. In addition, generally, pill-burden concerns and patient-compliance issues both argue against splitting dosing into multiple tablets. Thus, one of skill in the art aware of the art-recognized issues of pill-burden and patient-compliance would understand the cited combination of prior art to suggest unit dosage forms of 25-30mg of oxandrolone. Moreover, as described in the Declaration, a person familiar with unit dose formulation could not predict from Metcalf and the cited combination of prior art which unit dosage form of oxandrolone would be effective to treat a given condition.

Applicant maintains that the invention as claimed is not obvious over the cited combination of prior art and, accordingly, applicant respectfully requests reconsideration and withdrawal of this ground of rejection.